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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10451, CMS-1450 (UB-04), CMS-R-131 and CMS-10280]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: New collection; Title of Information Collection: Evaluation and Development of Outcome Measures for Quality Assessment in Medicare Advantage and Special Needs Plans; Use: Quality improvement is a major initiative for the Centers for Medicare and Medicaid Services (CMS). With the passing of the Patient Protection and Affordable Care Act in March 2010, there is a focused interest in providing quality and value-based healthcare for Medicare beneficiaries. In addition, it is critical to develop criteria not only for quality improvement but also as a means for beneficiaries to compare healthcare plans to make the choice that is right for them.

It is critical to the CMS mission to expand its quality improvement efforts from collection of structure and process measures to include outcome measures. However, the development of outcome measures appropriate for the programs serving older and/or disabled patients has been somewhat limited. The development and subsequent implementation of outcome measures as part of the overall quality improvement program for CMS is crucial to ensuring that beneficiaries obtain high quality healthcare. In addition, process of care measures are needed that focus on the care needs of Medicare beneficiaries, such as factors affecting continuity of care and transitions.

This request is for data collection to test the use of new tools available to CMS to measure care pertinent to vulnerable beneficiaries where quality of care provided by Medicare Advantage Organizations (MAOs) should be closely monitored. The measures to be evaluated and developed upon approval of this request relate to (1) continuity of information and care from hospital discharge to the outpatient setting, (2) continuity between mental health provider and primary care provider (PCP), and (3) items that may be added to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey addressing language-centered care, cultural competence, physical activity, healthy eating, and caregiver strain.

Since the publication of the 60-day notice (77 FR 65391), the information collection request has been revised. The order of questions has been changed in some locations of the instrument. In addition, we have revised items to collect documentation about refusal to permit communication between the mental health provider and the primary care provider. Form Number: CMS-10451 (OCN: 0938-New); Frequency: Yearly, occasionally; Affected Public: Individuals or Households, Private sector – Business or other for-profits ; Number of

Respondents: 2,012; Total Annual Responses: 2,360; Total Annual Hours: 4,630. (For policy questions regarding this collection contact Susan Radke at 410-786-4450. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5; Use: Section 42 CFR 424.5(a)(5) requires providers of services to submit a claim for payment prior to any Medicare reimbursement. Charges billed are coded by revenue codes. The bill specifies diagnoses according to the International Classification of Diseases, Ninth Edition (ICD-9-CM) code. Inpatient procedures are identified by ICD-9-CM codes, and outpatient procedures are described using the CMS Common Procedure Coding System (HCPCS). These are standard systems of identification for all major health insurance claims payers. Submission of information on the CMS-1450 permits Medicare intermediaries to receive consistent data for proper payment. Form Numbers: CMS-1450 (UB-04) (OCN: 0938-0997); Frequency: Reporting – On occasion; Affected Public: Not-for-profit institutions, Business or other for-profit; Number of Respondents: 53,111; Total Annual Responses: 181,909,654; Total Annual Hours: 1,567,455. (For policy questions regarding this collection contact Matt Klischer at 410-786-7488. For all other issues call 410-786-1326.)

3. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Advance Beneficiary Notice of Noncoverage (ABN); Use: The use of written notices to inform beneficiaries of their liability under specific conditions has been available since Title XVIII of the Social Security Act (the Act), section 1879, Limitation On Liability, was enacted in 1972 (P.L. 92-603). Similar required notification and liability

protections are available under other sections of the Act: section 1834(a)(18) refund requirements for certain items when unsolicited telephone contacts are made, section 1834(j)(4) for the same types of items when there is neither a required advance coverage determination nor required supplier number; section 1834(a)(15) also for advance determinations for these items and section 1842(l) applicable to physicians not accepting assignment. Implementing regulations are found at 42 CFR 411.404(b) and (c), and 411.408(d)(2) and (f), on written notice requirements. These statutory requirements apply only to Original Medicare, not Medicare Advantage plans.

Under section 1879 of the Act, Medicare beneficiaries may be held financially responsible for items or services usually covered under Medicare, but denied in an individual case under specific statutory exclusions, if the beneficiary is informed prior to furnishing the issues or services that Medicare is likely to deny payment.

When required, the ABN is delivered by Part B paid physicians, providers (including institutional providers like outpatient hospitals) practitioners (such as chiropractors), and suppliers, as well as hospice providers and Religious Non-medical Health Care Institutions paid under Part A. Other Medicare institutional providers paid under Part A use other approved notice for this purpose.

The revised ABN in this information collection request incorporates expanded use by Home Health Agencies (HHAs). There have been no substantive changes to the form. There are no changes that will affect existing ABN users. Form Number: CMS-R-131 (OMB#: 0938-0566); Frequency: Reporting – Occasionally; Affected Public: Private Sector – Business or other for-profits and Not-for-profit institutions; Number of Respondents: 1,288,837; Total Annual

Responses: 52,967,771; Total Annual Hours: 6,177,101. (For policy questions regarding this collection contact Evelyn Blaemire at 410-786-1803. For all other issues call 410-786-1326.)

4. Type of Information Collection Request: New collection; Title: Home Health Change of Care Notice (HHCCN); Use: Home health agencies (HHAs) are required to provide written notice to original Medicare beneficiaries under various circumstances involving the initiation, reduction, or termination of services. The notice used in these situations has been the Home Health Advance Beneficiary Notice (HHABN), CMS-R-296.

The HHABN, originally a liability notice specifically for HHA issuance, was first approved for use and implementation in 2000 with the home health prospective payment system transition. In 2006, the notice underwent significant modifications subsequent to the decision of the US Court of Appeals (2nd Circuit) in Lutwin v. Thompson. HHABN content and formatting were revised so that it could be used to provide beneficiaries with change of care notification consistent with HHA Conditions of Participation (COPs) in addition to its liability notice function. Three interchangeable option boxes were introduced to the HHABN to support the added notification purposes. Option Box 1 addressed liability, Option Box 2 addressed change of care for agency reasons, and Option Box 3 addressed change of care due to provider orders. HHABN Collection 0938-0781 last received PRA approval in 2009 following minor notice changes such as accessibility reformatting for compliance with Section 508 of the Rehabilitation Act of 1973, as amended in 1998, and removal of the beneficiary's health insurance claim number (HICN).

In an effort to streamline, reduce, and simplify notices issued to Medicare beneficiaries, HHABN Option Box 1, the liability notice portion, will be replaced by the existing Advanced

Beneficiary Notice of Noncoverage (ABN) which is approved by OMB (0938-0566), for conveying information on beneficiary liability. Written notices to inform beneficiaries of their liability under specific conditions have been available since the "limitation on liability" provisions in section 1879 of the Social Security Act were enacted in 1972 (P.L. 92-603). The ABN (CMS-R-131) is presently used by providers and suppliers other than HHAs to inform fee for service (FFS) Medicare beneficiaries of potential liability for certain items/services that might be billed to Medicare. The HHABN was developed specifically as the liability notice for HHA issuance. Since 2006, the HHABN has evolved to serve both liability and change of care notification purposes. Pursuant to a separate PRA package revising the use of the ABN, HHAs will now use the ABN for liability notification, and the HHCCN will be introduced as a separate, distinct document to give change of care notice in compliance with HHA conditions of participation. The HHCCN will replace both Option Box 2 and Option Box 3 formats of the HHABN. The single page format of the HHCCN is designed to specify whether the change of care is due to agency reasons or provider orders. Form Number: CMS-10280 (OCN: 0938-New); Frequency: Occasionally; Affected Public: Private Sector – Business or other for-profits and not-for-profit institutions; Number of Respondents: 10,914; Total Annual Responses: 14,126,428; Total Annual Hours: 941,385. (For policy questions regarding this collection contact Evelyn Blaemire at 410-786-1803. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at http://www.cms.hhs.gov/PaperworkReductionActof1995, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to

Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on **[insert date 30 days after date of publication in the Federal Register.]**

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-6974

E-mail: *OIRA_submission@omb.eop.gov*

Dated: February 20, 2013 _____

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

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